As you may be aware, it is imperative that all guidelines be created in a manner that is unbiased, easy to understand, and supported with relevant clinical/scientific evidence. Hundreds of thousands of clinicians rely on your reference materials to assist them in making their clinical decisions on product, or clinical practice. Hence, it is with this thought that I would like to share my concerns with you surrounding the content of your new "Draft Guidance" for the Prevention of Intravascular Catheter-Related Infections.

The topic of intravenous access ports/caps/devices has been an active area of interest and debate over the past several years, with organizations such as INS, AVA, APIC, SHEA, just to name a few. Interestingly enough, the numerous published articles seem to frequently send clinicians into a whirlwind of confusion and controversy, not clearly setting fourth relevant clinical information that could be used to provide accurate, unbiased, scientific evidence for product selection/utilization within a respected healthcare organization.

In example, an excellent Intravenous Access Cap which I have utilized at numerous facilities with exceptional results *did not* fall into either "categories" mentioned within the draft. The Clear Swabable Positive Displacement cap has a flat surface design feature, along with not having the concerning interstitial space that other products have been known to have. This space has always been known to contain moisture and potential bacterial growth/contamination within the inside of the cap.

More so, prior to my IV cap product selection process, I had the opportunity of conducting an extensive review of the numerous research studies and literature pertaining to this topic, along with the regulatory guidelines set fourth to assure the highest level of patient-safety. One of the most reputable resources that I had considered prior to our facilities cap selection was from the CDC's, "2008 Guidelines for Disinfection and Sterilization." This particular document outlined the significance of assuring that factors (such as surface details: crevices) allow for proper surface disinfection during the swabbing process. Hence, IV catheter hub surfaces have been seen as one of the most important surfaces that can be disinfected within a healthcare setting. The Clear Swabable Positive Displacement connector in use at my facility has certainly met surface decontamination requirements, and has dramatically decreased the bloodstream infection rates at my facility.

Industry Leaders such as Dr. Jarvis and Robert Garcia have also concluded that needleless devices should contain smooth, flat surfaces for optimal disinfection. Mr. Garcia had also signified the importance of the device not having an interstitial space, having an advanced seal design, positive fluid pulse, and high flow rates. These important factors being relevant to the overall CLABSI reduction efforts within the healthcare industry.

It is also important to note that even the Food & Drug Administration (FDA) had developed guidelines for the appropriate engineering/testing of IV caps in accordance with best practices and real-world patient scenarios. For example, the FDA guidelines dated 2005 indicate for product validation of the IV cap by conducting microbial ingress studies after repeat insertions with the same luer, as is done with intermittent therapy within a clinical setting. I find it astounding that very few manufacturers test their products in accordance with these 2005 FDA Guidelines. Rather, they conduct in-house bench-top studies which are heavily biased and scientifically flawed.

Two important studies (which were not referenced in the SHEA Compendium and in this draft guideline), mention valuable information that unfortunately was not utilized in the development of the "Guidelines." The information in these two studies alone could have changed the integrity of the compendium's information surrounding needless access devices and should be reviewed and included as cited reference in the new CDC guideline. These two studies are:

- Costello, et al. Systematic Intervention to Reduce Central Line Associated Bloodstream Infection Rates in a Pediatric Intensive Care Unit. Pediatrics 2008; 121;915-923 DOI: 10.1542/peds/2007-1577
    - A change from the Baxter Clearlink to the MaxPlus needleless access cap resulted in a decreased infection rate (4.7 to 2.3 CLRBSI's per 1,000 catheter days).

- Garcia, et al. A Study of the Effects on Bacteremia and Sharps Injury Rates After Introduction of an Advances Luer Activated Device (LAD) for Intravascular Access in a Large Hospital Setting. Abstract/Poster presented at the 2007 National APIC Conference.
  - In this particular study, the Interlink (split septum cap) was compared to the FloLink (aka MaxPlus) needleless access cap. The study indicated for a significant decrease of needlesticks, along with a decreased (and maintained) overall CLRBSI rate.

The differing classifications of needleless access caps have also created a myriad of misinterpretations and overall confusion among end users within the intravenous access industry. Numerous vendors, researchers, and professional societies, seem to all refer to these IV devices with differing terminology. Some refer to them as caps, while others use valves, or caps in their descriptions, not to mention the "pressure," or "displacement" that is frequently associated with a handful of the products distributed throughout the country.

The Clear Swabable Positive Displacement Connector utilized in my facility is neither a "mechanical valve," nor is a "split septum" device. The device is accessed with a luer, which in turn "compresses and rebounds" an internal, non-porous piece of silicone. Unlike any other caps, this particular silicone piece is not pierced, hence is highly resistant to degradation upon numerous accesses. More so, due to the fact that there are no internal parts that move independent of one another, there is no interstitial space which is very important on the prevention of biofilm formation and or contamination within the cap's internal anatomy.

In reiteration, Sections 1078, 1079, 1612 and 1613 clearly indicate for the assumption that split septum technology is preferred technology over mechanical valves due to increased risk of infection. The references used to make this recommendation are not scientifically relevant. More so, the recommendation states that split septum technology is preferred, however one will notice that split septum technology is actually an old design (external cannula activated technology) dating back to the early 1990's.

The articles used to support the split septum recommendation did not utilize the newer luer activated split septum technology, yet the way the recommendation is worded it could be construed that the CDC is recommending the use of this luer activated split septum technology which is not supported by the cited references. The references utilized to support

the CDC recommendation were "before and after" data collection studies that utilized one specific external cannula activated split septum device (Interlink), one specific positive pressure mechanical valve device (SmartSite Plus), and one specific negative pressure mechanical valve device (SmartSite); thus the entire recommendation is based on results of comparing basically two different valve technologies from two different manufacturers, as the SmartSite Plus and SmartSite basically incorporate the same exact design. There are numerous (10 or more) connectors/valves available, and many of these devices have been studied with demonstrated positive results (ex. Costello, et al), which were not included when drafting this recommendation. The specific call out for the use of split septum technology (when basically only one manufacturer offers this old multi part technology) is not clinically sound, ethical or scientifically based.

It can also be noted that the simplistic, yet advanced design of the Clear Swabable Positive Displacement connector utilized at my facility allows for optimal and complete priming and flushing, ultimately preventing reflux by means of its positive "displacement." After every access of the internal silicone piece relaxes and is also visually confirmed by end-user clinicians. Unfortunately, all of the competing vendors have flooded the marketplace with propaganda and irrelevant home-based research studies that in my opinion have proven detrimental to patient care in hospitals throughout the world.

In closing, I truly hope that the CDC removes the statement that split septum technology is preferred. This technology is old dating back to the 1990's, it requires a special blunt cannula to access it requiring hospitals to purchase more parts, it can still be accessed with a needle make compliance with OSHA regulations and needlestick prevention difficult. There are several needleless connector systems available that offer clinicians and ultimately patients protection. To revert back over a decade in research and development on this topic and recommend old technology seems to me like something an agency such as the CDC would not want to do. I truly hope the CDC broadens its product evaluation process in the final version of the Guideline, assuring that all products are compared equally, with unbiased scientific and clinical relevance. Patients' trust healthcare organizations when they are hospitalized or seek medical care. We, as clinicians, should also be able to trust our resources/references, when making decisions that significantly impact patient care.

Respectfully Submitted,

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